



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/012,194	12/06/2001	Manuela Martins-Green	407E-914500US	5287
22798	7590	11/02/2005	EXAMINER	
QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501			QIAN, CELINE X	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/012,194	Applicant(s) MARTINS-GREEN ET AL.	
	Examiner Celine X. Qian Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6,9-15,18-20,23,25,26,43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-6,9-15,18-20,23,25,26,43 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1636

DETAILED ACTION

Claims 2-6, 9-15, 18-20, 23, 25, 26, 43 and 44 are pending in the application.

Response to Amendment

Acknowledgement is made of Applicant's submission of corrected drawings.

The rejection of claims 9, 13 and 14 under 35 U.S.C.112 2nd paragraph has been withdrawn in light of Applicant's amendment of the claims.

Claims 2-6, 9-15, 18-20, 23, 25, 26, 43 and 44 are rejected under 35 U.S.C.103 (a) for reasons discussed below.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6, 9-15, 18-20, 23, 25, 26, 43 and 44 rejected under 35 U.S.C. 103(a) as being unpatentable over Black et al., in view of Fransson et al (British Journal of Dermatology, 1998, Vol 139: pages 59--604) and Montesano et al..

Black et al. teach a skin equivalent preparation comprising human keratinocytes plated on endothelial dermal equivalent or endothelial fibroblast dermal equivalent mixed with collagen (see page 1333, 1st col., 2nd and 3rd paragraph). Black et al. also teach that the endothelial fibroblast dermal equivalent comprising fibroblast and HUVEC (see page 1333, 1st col., 2nd paragraph). Black et al. further teach that a network of capillary-like tubular structures is formed

Art Unit: 1636

in the tissue (see page 1333, 2nd col., 3rd and 5th paragraph). Furthermore, Black et al. teach that said tissue produces laminin, type IV collagen and extracellular matrix (see page 1334, 1st col., 2nd paragraph, and Figures 1, 2 and 3). Moreover, Black et al. disclose that said tissue is self maintained *in vitro*, and is suitable for tissue graft (see page 1338, entire 1st col., and 2nd col., 2nd paragraph).

However, Black et al. do not teach an artificial tissue comprising two layers of support matrix-connective tissue mixture separated by a layer of endothelial cells. Black et al. do not teach said microvessel that produces mononuclear leukocytes.

Montesano et al. teach endothelial cell monolayers established on the surface of collagen matrix and covered with another layer of collagen matrix induces the endothelial cells to reorganize into a network of branching and anastomosing capillary-like tubes resembling capillary beds *in vivo* (see page 1649, 2nd col., 3rd paragraph, lines 1-4). Montesano et al. further teach that an appropriate topological relationship of endothelial cells with collagen matrices, similar to that occurring *in vivo*, has an inductive role for endothelial cells to form vessel-like structures *in vitro* (see abstract).

Fransson et al. teach that a *in vitro* cultured skin equivalent that comprises mononuclear leukocytes which expresses CD 86 and CD 80 (see page 603, 1st col., 1st paragraph).

It would have been obvious to one of ordinary skill in the art to make an artificial skin equivalent as taught by Black et al. and introduce a second layer of connective tissue on top of the endothelial cell based on the teaching of Montesano et al. One of ordinary skill in the art would have been motivated to do so because it would resemble the capillary bed *in vivo* and thus induce capillary formation closely resemble that of *in vivo* setting, as demonstrated by

Art Unit: 1636

Montésano et al. The ordinary artisan would also have been motivated to add LC cells to the culture so that the immature antigen presenting cells can be produced and the skin equivalent can be used as an allergy model. The level of skill in the art is high. Absent evidence from the contrary, one of ordinary skill in the art would have reasonable expectation of success to make the tissue as claimed. Therefore, the claimed invention would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.
Examiner
CELIAN QIAN 1636
PATENT EXAMINER

